

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings replaces all earlier submitted drawing sheets. The attached sheet includes a change to Figure 3. The change is identified by a hand-drawn arrow in the attached “annotated” sheet.

Attachment: Replacement Sheet(s)
Annotated Sheet Showing Changes

REMARKS

The objection to the drawings has been overcome by adding a pump to the drawings.

The drawings are objected to as not showing a pump. Figure 3 have been amended to indicate pump which is shown illustratively as a circle labeled 232 to illustrate a roller pump. Reference number 232 has been added to paragraph 0020. The addition of the roller/tube track of a pump to the drawings does not introduce new subject matter because pumps are described in the original application at, for example, paragraphs 0020 and original claim 8 refers to a "pump section" of the extracorporeal blood circuit.

The rejection of claims 1, 14, 19, 29 and 20 as lacking a written description is traversed and has been overcome by amendment.

The claims have been amended so that a pump and extracorporeal circuit are not positively recited as elements of the invention which is directed to a blood passage, e.g., tube.. The inventive blood passage is adapted to be coupled to a pump in an extracorporeal circuit. The claims have been amended to state that the blood passage is "adapted" to be positioned in a pump of an extracorporeal blood circuit. These statements in the claims assist in defining the invention to make more distinct the portion of the blood passage that is to be inserted in the pump and the portion that is not in the pump. The rejection should be withdrawn because the claims do not positively recite a pump or extracorporeal circuit.

The rejection of claims 1, 2 and 4 to 31 as being obvious over Sunden (US Patent 6,494,693) in view of Raible et al (US Patent 4,954,055) is traversed.

The independent claims 1, 15, 19 and 31 require a narrow tube section that is at least as long as one-half of the entire length of the tube. This feature is not shown in Sunden or Raible.

Sunden does not teach a narrow section that is at least one half the length of the blood tube for the reasons discussed above. Further, the claims define a “pump tube section” that is distinct from the narrow tube section. In contrast, Sunden discloses a small diameter pump tube section and provide no suggestion of a narrow tube section that is distinct from the pump tube section, as is required by the rejected claims.

Raible teaches away from the claimed invention by disclosing a tube having small diameter ends and a large diameter center section. Raible teaches away from a narrow section between the pump section of the tube and the inlet/outlet to the tubes, as is recited in the rejected claims. Sunden and Raible teach opposite approaches to a pump section of a blood tube. Sunden teaches a narrow tube section that engages a pump and Raible teaches a large diameter tube section to engage a pump. Given these conflicting teachings, it is not seen how these two references can be combined or the shape of a blood tube that would result from such a combination. Accordingly, the combination of Raible and Sunden would not have rendered obvious independent claims 1, 15, 19 and 31.

Independent claim 27 requires first and second middle portions of the tube having a small inside diameters that is smaller than the inside diameter of a first end of the tube and of a pump section of the tube between the first and second middle portions. As discussed above, Sunden does not disclose a middle section of a blood tube that is distinct from the pump section of the tube and has the dimensional features recited in claim 27. Raible does not

disclose a narrow diameter middle section of the blood tube. The combination of Sunden and Raible does not yield a blood tube as recited in claim 27.

Claims 29 and 30 make clear that the narrow tube section is distinct from the pump tube section. These claims require that the narrow tube section be a different portion of the tube than the pump tube section. The amendment to claims 29 and 30 make more clear that the length of the narrow tube section does not including the pump tube section and extends at least one half the length of the entire tube. This feature is not disclosed or suggested in Sunden.

In particular, Sunden does not disclose the following limitation of claim 29:

wherein said narrow section is distinct from the pump tube section and comprises at least one half of an entire length of the blood tube and wherein said length of the blood tube includes the first end, first tapered tube transition section, narrow section, pump tube section, second tapered tube transition section and second end.

The above “narrow section” limitation distinguishes Sunden that shows a narrow diameter “pump tube” which is a short blood tube that engages a pump. Sunden does not suggest that sections of a blood tube be narrow, other than at the portion of the tube engaging the pump (which is referred to in the claim as the “pump tube section”). A length of blood tube that fits into a pump (as taught by Sunden) does not constitute at least half of an entire tube as required by claim 29. Further, Sunden does not teach a large diameter tube section in addition to a narrow blood tube as is recited in the claims.

The Action at page 8 correctly recognizes that “Sunden fails to disclose the proportional length of the tubing sections.” Claims 29 and 30 require the proportional length of the narrow tube section to be less than one-half of the length of the entire tube. The Action gives no patentable weight to the requirement for the proportional length of the narrow tube section.

The proportional requirement in claim 29 is a structural limitation and should be given patentable weight. MPEP 2114 (“Apparatus Claims Must Be Structurally Distinguishable From The Prior Art”). The structure recited in claims 29 and 30 requires a blood tube that has a narrow diameter for at least one-half of its length, wherein the portion of the tube to be engaged with a pump is not part of the narrow diameter section that is at least half the length of the pump. The structural requirement regarding the length of the narrow diameter section relates to an advantage that tube (as defined by claims 29 and 30) has with respect to prior art tubes. In particular, the tube defined by claims 29 and 30 has an extended narrow diameter section to reduce the internal volume of the blood tube and thereby reduce the volume of blood in an extracorporeal circuit including the blood tube. The specification at paragraph 0004 describes the advantage of a reduced internal volume in the blood tube as:

Minimizing the volume of the blood flow passage in an extracorporeal circuit generally reduces the amount of time the blood is in the extracorporeal circuit for a given blood flow rate. Minimizing the blood passage volume also reduces the volume of blood lost if a clot forms to block the circuit (and cause the

blood flow to cease and the circuit filled with blood to be discarded).

These advantages of the claimed blood tube are not present in the blood pump tube loop disclosed in Sunden. There is no recognition in Sunden of a need to reduce the volume of a blood flow passage to minimize the amount of time blood is in an extracorporeal circuit. Accordingly, Sunden would not have provided sufficient information to a person of ordinary skill in the art to have rendered the claimed invention to have been obvious.

With respect to the dependent claims, the combination of Raible and Sunden do not disclose:

- a narrow section that is not engaged with a pump, as recited in claim 2.
- a constant wall section, as recited in claims 5, 16, 17, 21, 22. Raible does not disclose the wall thickness of a blood tube. Sunden appears to show a change in the wall thickness in Figures 2B, 2C and 2D, but the text of Sunden does not discuss the wall section thickness of a blood tube.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Steven Bernard et al
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Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Jeffry H. Nelson/

Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100